

Remarks/Arguments

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed April 30, 2008 and the Advisory Action of the Examiner mailed August 14, 2008. Currently, claims 1-48 and 51-55 remain pending. Claims 1-48 and 51-55 have been rejected. In this amendment, claim 1 has been amended and newly presented claims 56-61 have been added. Favorable consideration of the following remarks is respectfully requested.

Status of Claims

In the Advisory Action mailed August 14, 2008, the Examiner indicated that the Amendment After-Final filed on July 30, 2008 will not be entered. As such, the current status of the claims is based on the claims prior to the Amendment After-Final filed July 30, 2008.

Claim Rejections – 35 USC § 102

On page 2 of the Final Office Action, claims 1, 28-30, 32-33, and 35-40 were rejected under 35 U.S.C. 102(e) as being anticipated by Gumm (U.S. Publication No. 2003/0055483). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Currently Amended) A catheter assembly comprising:
a catheter shaft, the catheter shaft having a length and an outer surface;
a balloon, the balloon comprising a proximal balloon waist, a distal balloon waist and a body portion therebetween, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter; and
~~and~~—a proximal collar and a distal collar, the proximal collar fixed engaged to the catheter shaft and the distal collar fixed engaged to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar, in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon ~~collar~~ waist.

Without conceding the correctness of the Examiner's rejection, Applicant has amended claim 1 to further distinguish claim 1 from the cited art in order to further prosecution in this case.

As amended, claim 1 recites “a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar, in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist”. Nowhere does Gumm appear to teach or suggest at least these limitations of claim 1.

Instead, Gumm appears to teach a catheter assembly having a rotatably mounted balloon that can be advanced to a vessel bifurcation along first and second guidewires. (See abstract). The catheter assembly appears to include a tubular member or hypotube 14 have a distal fixed body 20 and a proximal fixed body 22 non-rotatably secured to the distal end and proximal end of the hypotube 14. (See paragraph 39). A first rotating member, or distal rotating member 24, and a second rotating member, or proximal rotating member 26, are axially spaced apart and located between the distal fixed body 20 and proximal fixed body 22. The rotating members 24 and 26 appear to be configured to rotate freely about the axis of the main hypotube 14. (See paragraph 40). A catheter balloon 28 is sealed to the proximal and distal rotating members 24 and 26. (See paragraph 41). “A distal end 30 of the catheter balloon is sealingly joined to (or integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube” (paragraph 41). (Emphasis added).

As can be clearly seen, Gumm appears to teach the proximal and distal rotating members joined to or integrally formed with the balloon to allow the balloon to freely rotate about the main hypotube. Clearly, the proximal and distal rotating members are not fixed to the catheter shaft. As such, nowhere does Gumm appear to teach or suggest “a proximal collar and a distal collar, the proximal collar fixed to the catheter shaft and the distal collar fixed to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar”, as recited in claim 1.

Furthermore, nowhere does Gumm appear to teach or suggest “each collar having a nonactivated state and an activated state ... in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist”. Instead, Gumm appears to teach or suggest axial movement and/or pressurizing the balloon to seal the rotating members to the main hypotube.

In the Final Office Action, the Examiner cites paragraph 41 and 45 as teaching or suggesting “the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist”. The cited passages recite:

[0041] Sealed to the proximal and distal rotating members 24 and 26 are opposite ends of a catheter balloon 28. A distal end 30 of the catheter balloon is sealingly joined to (or integrally formed with) the distal rotating member 24 while a proximal end 32 of the catheter balloon is sealingly joined to (or integrally formed with) the proximal rotating member 26. Thus, the balloon is free to rotate relative to the main hypotube, a feature that provides advantages and benefits over known stent assemblies. It is also contemplated that the rotating members 24 and 26 can be formed of sealing or elastomeric material (or incorporate a separate seal member) so that slight axial movement of the balloon 28 and of the rotating members 24 and 26 engages and seals against the fixed bodies 20 and 22 upon inflation of the balloon 28. The balloon 28 and the rotating members 24 and 26 can hold high pressure and seal at the ends. It will be appreciated that the rotating members 24 and 26 are preferably constructed to maintain a cylindrical configuration under pressure so that the balloon 28 is free to rotate relative to the main hypotube 14 when pressurized.

[0045] An enlarged view of the side branch hypotube opening 64 in the stent 50 is shown in FIG. 5. The side branch hypotube 60 exits from underneath the proximal end of the stent. Upon deployment of the stent 50, the side branch hypotube opening 64 allows for unobstructed blood flow to the ostium of the side branch passage. As will also be appreciated, the side branch hypotube 60 is fixed or secured to the exterior of the balloon. Thus, the side branch hypotube 60, balloon 28, and rotating members freely rotate as a unit relative to the main hypotube 14 for accurate, passive positioning with the side guide wire and thus accurate positioning of the stent 50 relative to a saddle point of the bifurcated passage. With continued reference to FIG. 2, the catheter balloon 28 is inflated, the stent 50 is deployed, and the rotating members 24 and 26 are interlocked with the fixed members 20 and 22 to stop the rotating action of the stent delivery system and create a pressure tight system.

Nowhere do these passages appear to teach or suggest the rotating members 24 and 26 being expandable. Additionally, no other portion of Gumm appears to teach or suggest “each collar having a nonactivated state and an activated state ... in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon waist”, as recited in claim 1.

As the Examiner is well aware, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (MPEP § 2131). As discussed previously, Gumm appears to fail to teach each and every element of claim 1. Therefore, for at least these reasons, claim 1 is believed to be clearly not anticipated by Gumm and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 28-30, 32-33, and 35-40, which depend from claim 1 and include additional limitations, are believed to be clearly not anticipated by Gumm.

Claim Rejections – 35 USC § 103

On page 4 of the Final Office Action, claims 16-19 and 31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Gerberding et al. (U.S. Patent No. 6,315,790). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Gerberding et al. appears to remedy the above-noted shortcomings. Therefore, claims 16-19 and 31, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Gerberding et al.

On page 5 of the Final Office Action, claim 34 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Marton (U.S. Publication No. 2001/0032013). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Marton appears to remedy the above-noted shortcomings. Therefore, claim 34,

which depends from claim 1 and includes additional limitations, is believed to be clearly patentable over Gumm in view of Marton.

On page 5 of the Final Office Action, claims 41, 42, and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Pinchuk et al. (U.S. Publication No. 2002/0107330). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 41, 42, and 46, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

Applicant notes that while referring to claims 51-55, the Examiner states that "Gumm in view of Pinchuk discloses the invention substantially as claimed". However, nowhere in the Final Office Action does the Examiner expressly rejected claims 51-55. Applicant reminds the Examiner that "[w]here a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated, and the word "reject" must be used." (MPEP § 707.07). However, for similar reasons discussed previously, and others, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 51-55, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

On page 6 of the Final Office Action, claims 43-45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (U.S. Publication No. 2003/0055483) in view of Pinchuk et al. (U.S. Patent No. 2002/0107330). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Gumm and nothing in Pinchuk et al. appears to remedy the above-noted shortcomings. Therefore, claims 43-45, which depend from claim 1 and include additional limitations, are believed to be clearly patentable over Gumm in view of Pinchuk et al.

Completeness of Office Action

In the Final Office Action, the Examiner only addressed claims 1, 16-19, 28-46, and 51-55. Nowhere does the Examiner appear to address pending claims 2-15, 20-27, and 47-48. As the Examiner is well aware, MPEP § 707.07 states:

37 CFR 1.104. Nature of examination.

(b)Completeness of examiner's action. The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

Applicant respectfully requests that the Examiner address every pending claim in the next Office Action so that Applicant may be provided with an opportunity to respond. Because the Examiner failed to rejection claims 2-15, 20-27, and 47-48, Applicant believes that claims 2-15, 20-27, and 47-48 contain allowable subject matter. Accordingly, Applicant respectfully requests that the Examiner indicate that claims 2-15, 20-27, and 47-48 contain allowable subject matter in the next Office Action.

Newly Presented Claims

With this Amendment, Applicant has added newly presented claims 56-61. For similar reasons discussed above, as well as other reasons, newly presented claims 56-61 are believed to be patentable over the cited references.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By his Attorney,

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